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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,708	12/20/2001	Michael R. Boyd	213045	9974

23460 7590 06/16/2004

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER	
MITCHELL, GREGORY W	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,708	BOYD, MICHAEL R.	
	Examiner	Art Unit	
	Gregory W Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17 and 31 (each in part), drawn to a method of treating individuals by inhibiting vacuolar-type (H+)-ATPase. The invention of Group I comprises the administration of a composition comprising a compound and a carrier. Said composition is characterized by a 5-17 membered lactone ring (Z = 0-12 atoms) wherein all Z atoms are carbon.

Group II, claim(s) 1-17 and 31 (each in part), drawn to a method of treating individuals by inhibiting vacuolar-type (H+)-ATPase. The invention of Group II comprises the administration of a composition comprising a compound and a carrier. Said composition is characterized by a 5-17 membered lactone ring (Z = 0-12 atoms) wherein at least one Z atom is a nitrogen.

Group III, claim(s) 1-17 and 31 (each in part), drawn to a method of treating individuals by inhibiting vacuolar-type (H+)-ATPase. The invention of Group III comprises the administration of a composition comprising a compound and a carrier. Said composition is characterized by a 5-17 membered lactone ring (Z = 0-12 atoms) wherein at least one Z atom is either an oxygen or a sulfur.

Group IV, claim(s) 1-17 and 31 (each in part), drawn to a method of treating individuals by inhibiting vacuolar-type (H+)-ATPase. The invention of Group IV comprises the administration of a composition comprising a compound and a carrier. Said composition is characterized by a 5-17 membered lactone ring (Z = 0-12 atoms) wherein at least one Z atom is a nitrogen and at least one other Z atom is an oxygen or sulfur.

Group V, claim(s) 1-17 and 31 (each in part), drawn to a method of treating individuals by inhibiting vacuolar-type (H+)-ATPase. The invention of Group V comprises the administration of a composition comprising a compound and a carrier.

Said composition is characterized by a 5-17 membered lactone ring (Z = 0-12 atoms) wherein all Z atoms are carbon and the lactone ring is further fused with an epoxide ring.

Group VI, claim(s) 18, 19, 20 and 21-30 (each in part), drawn to a composition comprising a lactone and a carrier. Group VI is limited to those inventions wherein Z is 0-6 atoms (forming a 5-11 membered lactone ring), said atoms consisting solely of carbon atoms.

Group VII, claim(s) 18, 19, 20 and 21-30 (each in part), drawn to a composition comprising a lactone and a carrier. Group VII is limited to those inventions wherein Z is 1-6 atoms (forming a 6-11 membered lactone ring) and at least one Z atom is a nitrogen atom.

Group VIII, claim(s) 18, 19, 20 and 21-30 (each in part), drawn to a composition comprising a lactone and a carrier. Group VIII is limited to those inventions wherein Z is 1-6 atoms (forming a 6-11 membered lactone ring) and at least one Z atom is an oxygen or sulfur atom.

Group IX, claim(s) 18, 19, 20 and 21-30 (each in part), drawn to a composition comprising a lactone and a carrier. Group VII is limited to those inventions wherein Z is 2-6 atoms (forming a 7-11 membered lactone ring) and at least one Z atom is a nitrogen atom and at least one other Z atom is an oxygen or sulfur atom.

Group X, claim(s) 18, 19, 20 and 21-30 (each in part), drawn to a composition comprising a lactone and a carrier. Group VI is limited to those inventions wherein Z is 0-6 atoms (forming a 5-11 membered lactone ring), said atoms consisting solely of carbon atoms, and wherein an epoxide ring is fused with the lactone ring.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I lacks unity with the invention of Group II because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. A nitrogen containing lactone used in the invention of Group II

will, for example, have a greater nucleophilicity and a stronger basicity than will a non-nitrogen containing lactone used in the invention of Group I.

The invention of Group I lacks unity with the invention of Group III because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. An oxygen or sulfur containing lactone used in the invention of Group III will, for example, have a greater electrophilicity, a greater polarity and an increased hydrophilicity compared to a lactone ring possessing only the lactone oxygen in its backbone (used in the invention of Group I) due to the increased electronegativity of and electron density surrounding the oxygen or sulfur atom.

The invention of Group I lacks unity with the invention of Group IV because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. A nitrogen and oxygen or sulfur containing lactone used in the invention of Group IV will, for example, have a greater nucleophilicity, a stronger basicity and polarity than will a non-nitrogen and oxygen or sulfur containing lactone used in the invention of Group I.

The invention of Group I lacks unity with the invention of Group V because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be

different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The epoxide used in the treatment of Group V will significantly alter the stability of a compound. Epoxides are known to be especially susceptible to nucleophilic attack and ring opening due to a weak carbon-oxygen bond caused by angle strain. Furthermore, the presence of the epoxide oxygen will cause a compound used in a Group V treatment to have an increased polarity and hydrophilicity, thereby increasing the bioavailability of the compounds used in Group V treatments.

The invention of Group I lacks unity with the inventions of Groups VI-X because they do not share a common special technical feature. The compositions used in the treatments of Group I do not have the same scope as do the compositions claimed in the inventions of Groups VI-X because the special technical feature of Group I is drawn to a 5-17 membered lactone ring whereas the inventions of Groups VI-X are drawn to 5-11 membered lactone rings. For example, a treatment comprising the administration of a 12 membered lactone ring to a patient would not share a special technical feature with a composition comprising a 5-11 membered lactone ring.

The invention of Group II lacks unity with the invention of Group III because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. An oxygen containing lactone used in the invention of Group III will, for example, have a greater electrophilicity and a greater polarity than an analogous

nitrogen containing lactone (used in the invention of Group II) due to the increased electronegativity of the oxygen atom.

The invention of Group II lacks unity with the invention of Group IV because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The reactivities of the lactones used in the treatments of Group IV are not going to depend solely on the presence of the nitrogen heteroatom as in the lactones used in the treatments of Group II but also on the oxygen and/or sulfur atom(s) of the heterocycle. Accordingly, the presence of the nitrogen heteroatom will not be predictive of the properties and/or reactivities in the nitrogen *and* oxygen and/or sulfur containing lactone. Furthermore, the two groups will be different because of varied polarities and solubilities of the compounds; hetero-containing lactones used in Group IV treatments will have competing electronegativities of the different heteroatoms whereas hetero-containing lactones of Group II will have a single type of heteroatom.

The invention of Group II lacks unity with the invention of Group V because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The epoxide used in the treatment of Group V will significantly alter the stability of a compound. Epoxides are known to be especially susceptible to nucleophilic attack and ring opening due to a weak carbon-oxygen bond caused by

angle strain. Furthermore, the presence of the epoxide oxygen will cause a compound used in a Group V treatment to have a polarity dissimilar to a lactone used in a Group II treatment because of differing nitrogen and oxygen electronegativities.

The invention of Group II lacks unity with the inventions of Groups VI-X because they do not share a common special technical feature. The compositions used in the treatments of Group II do not have the same scope as do the compositions claimed in the inventions of Groups VI-X because the special technical feature of Group II is drawn to a 5-17 membered lactone ring whereas the inventions of Groups VI-X are drawn to 5-11 membered lactone rings. For example, a treatment comprising the administration of a 12 membered lactone ring to a patient would not share a special technical feature with a composition comprising a 5-11 membered lactone ring.

The invention of Group III lacks unity with the invention of Group IV because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The reactivities of the lactones used in the treatments of Group IV are not going to depend solely on the presence of the oxygen or sulfur heteroatom as in the lactones used in the treatments of Group III but also on the oxygen and/or sulfur atom(s) of the heterocycle. Accordingly, the presence of the oxygen or sulfur heteroatom will not be predictive of the properties and/or reactivities in the nitrogen *and* oxygen and/or sulfur containing lactone. Furthermore, the two groups will be different because of varied polarities and solubilities of the compounds; hetero-containing

lactones used in Group IV treatments will have competing electronegativities of the different heteroatoms whereas hetero-containing lactones of Group III will have a single type of heteroatom.

The invention of Group III lacks unity with the invention of Group V because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The epoxide used in the treatment of Group V will significantly alter the stability of a compound. Epoxides are known to be especially susceptible to nucleophilic attack and ring opening due to a weak carbon-oxygen bond caused by angle strain. Furthermore, the presence of the epoxide oxygen will cause a compound used in a Group V treatment to have a solubility dissimilar to a lactone used in a Group III treatment because, for example, the hydrophilicity of an epoxide will not be the same as a typical ether because, as a result of the angle strain, the lone pairs of the epoxide oxygen are in a much lower energy state than they would be in a typical ether.

The invention of Group III lacks unity with the inventions of Groups VI-X because they do not share a common special technical feature. The compositions used in the treatments of Group III do not have the same scope as do the compositions claimed in the inventions of Groups VI-X because the special technical feature of Group III is drawn to a 5-17 membered lactone ring whereas the inventions of Groups VI-X are drawn to 5-11 membered lactone rings. For example, a treatment comprising the

administration of a 12 membered lactone ring to a patient would not share a special technical feature with a composition comprising a 5-11 membered lactone ring.

The invention of Group IV lacks unity with the invention of Group V because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The epoxide used in the treatment of Group V will significantly alter the stability of a compound. Epoxides are known to be especially susceptible to nucleophilic attack and ring opening due to a weak carbon-oxygen bond caused by angle strain. Furthermore, the presence of the epoxide oxygen will cause a compound used in a Group V treatment to have a solubility dissimilar to a lactone used in a Group IV treatment because, for example, the hydrophilicity of an epoxide will not be the same as a typical ether because, as a result of the angle strain, the lone pairs of the epoxide oxygen are in a much lower energy state than they would be in a typical ether.

The invention of Group IV lacks unity with the inventions of Groups VI-X because they do not share a common special technical feature. The compositions used in the treatments of Group IV do not have the same scope as do the compositions claimed in the inventions of Groups VI-X because the special technical feature of Group IV is drawn to a 5-17 membered lactone ring whereas the inventions of Groups VI-X are drawn to 5-11 membered lactone rings. For example, a treatment comprising the administration of a 12 membered lactone ring to a patient would not share a special technical feature with a composition comprising a 5-11 membered lactone ring.

The invention of Group V lacks unity with the inventions of Groups VI-X because they do not share a common special technical feature. The compositions used in the treatments of Group V do not have the same scope as do the compositions claimed in the inventions of Groups VI-X because the special technical feature of Group V is drawn to a 5-17 membered lactone ring whereas the inventions of Groups VI-X are drawn to 5-11 membered lactone rings. For example, a treatment comprising the administration of a 12 membered lactone ring to a patient would not share a special technical feature with a composition comprising a 5-11 membered lactone ring.

The invention of Group VI lacks unity with the invention of Group VII because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. A nitrogen containing lactone of Group VII compositions will, for example, have a greater nucleophilicity and a stronger basicity than will a non-nitrogen containing lactone of Group VI compositions.

The invention of Group VI lacks unity with the invention of Group VIII because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. An oxygen or sulfur containing lactone of Group VIII compositions will, for example, have a greater electrophilicity, a greater polarity and an increased hydrophilicity compared to a lactone ring possessing only the

lactone oxygen in its backbone (in Group VI compositions) due to the increased electronegativity of and electron density surrounding the oxygen or sulfur atom.

The invention of Group VI lacks unity with the invention of Group IX because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. A nitrogen and oxygen or sulfur containing lactone of Group IX compositions will, for example, have a greater nucleophilicity, a stronger basicity and polarity than will a non-nitrogen and oxygen or sulfur containing lactone of Group VI compositions.

The invention of Group VI lacks unity with the invention of Group X because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The epoxide of a composition in an invention of Group X will significantly alter the stability of the lactone. Epoxides are known to be especially susceptible to nucleophilic attack and ring opening due to a weak carbon-oxygen bond caused by angle strain. Furthermore, the presence of the epoxide oxygen will cause a compound of Group X compositions to have an increased polarity and hydrophilicity, thereby increasing the bioavailability of Group X compositions compared to Group VI compositions.

The invention of Group VII lacks unity with the invention of Group VIII because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. An oxygen containing lactone of Group VIII compositions will, for example, have a greater electrophilicity and a greater polarity than an analogous nitrogen containing lactone (Group VII compositions) due to the increased electronegativity of the oxygen atom.

The invention of Group VII lacks unity with the invention of Group IX because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The reactivities of the lactones used in the treatments of Group IX are not going to depend solely on the presence of the nitrogen heteroatom as in the lactones of Group VII compositions but also on the oxygen and/or sulfur atom(s) of the heterocycle. Accordingly, the presence of the nitrogen heteroatom will not be predictive of the properties and/or reactivities in the nitrogen *and* oxygen and/or sulfur containing lactone. Furthermore, the two groups will be different because of varied polarities and solubilities of the compounds; hetero-containing lactones of Group IX compositions will have competing electronegativities of the different heteroatoms whereas hetero-containing lactones of Group VII compositions will have a single type of heteroatom.

The invention of Group VII lacks unity with the invention of Group X because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The epoxide of Group X compositions will significantly alter the stability of the lactone. Epoxides are known to be especially susceptible to nucleophilic attack and ring opening due to a weak carbon-oxygen bond caused by angle strain. Furthermore, the presence of the epoxide oxygen will cause a compound of Group X compositions to have a polarity dissimilar to a lactone of Group VII compositions because of differing nitrogen and oxygen electronegativities.

The invention of Group VIII lacks unity with the invention of Group IX because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The reactivities of the lactones of Group IX compositions are not going to depend solely on the presence of the oxygen or sulfur heteroatom as in the lactones of a composition in an invention of Group VIII but also on the oxygen and/or sulfur atom(s) of the heterocycle. Accordingly, the presence of the oxygen or sulfur heteroatom will not be predictive of the properties and/or reactivities in the nitrogen *and* oxygen and/or sulfur containing lactone. Furthermore, the two groups will be different because of varied polarities and solubilities of the compounds; hetero-containing lactones of Group IX compositions will have competing electronegativities of

the different heteroatoms whereas hetero-containing lactones of Group VIII compositions will have a single type of heteroatom.

The invention of Group VIII lacks unity with the invention of Group X because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The epoxide of Group X compositions will significantly alter the stability of the lactone. Epoxides are known to be especially susceptible to nucleophilic attack and ring opening due to a weak carbon-oxygen bond caused by angle strain. Furthermore, the presence of the epoxide oxygen will cause a compound of Group X compositions to have a solubility dissimilar to a lactone of Group VIII compositions because, for example, the hydrophilicity of an epoxide will not be the same as a typical ether due to, as a result of the angle strain, the lone pairs of the epoxide oxygen being in a much lower energy state than they would be in a typical ether.

The invention of Group IX lacks unity with the invention of Group X because the types of atoms present in the lactone will strongly influence the nature of the compound used in the treatments of the two groups. The bioavailability of these compounds will be different because of the varying polarities, solubilities, reactivities, etc. of the different types of ring systems. The epoxide of Group X compositions will significantly alter the stability of the lactone. Epoxides are known to be especially susceptible to nucleophilic attack and ring opening due to a weak carbon-oxygen bond caused by angle strain. Furthermore, the presence of the epoxide oxygen will cause a compound of Group X

compositions to have a solubility dissimilar to a lactone of Group IX compositions because, for example, the hydrophilicity of an epoxide will not be the same as a typical ether due to, as a result of the angle strain, the lone pairs of the epoxide oxygen being in a much lower energy state than they would be in a typical ether.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If Applicant elects one of Groups I-V, Applicant is required, in reply to this action, to elect a single composition species (identifying a specific lactone) as well as a single condition species (identifying a specific condition to which administration of the lactone is intended to treat) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

If Applicant elects one of Groups VI-X, Applicant is required, in reply to this action, to elect a single composition species (identifying a specific lactone) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 12-17 are drawn to specific species of condition treated.

The following claim(s) are generic: 1-11 and 18-31.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure which is a significant structural element. Although the chemical compounds of the compositions of claims 1-31 share the common structure of an ene-amide, the compounds are not regarded as being of similar nature because the shared common structure is not a significant structural element. The significant structural element of the compound is the lactone. While each compound comprises a lactone, the lactone of each of the species is not the same. For example, one species of Group I could be a lactone comprising a 5 membered ring whereas another species of Group I could be a lactone comprising a 17 membered ring.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. All the species of Groups I-V are directed to "treating or preventing a condition" but each species has a special technical feature not shared by the remaining species. For example, one species is directed to the treatment of cancer, another to the treatment for the inhibition of intra-organellar acidification of intracellular organelles, and yet another to a treatment of osteoporosis.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was not made due to the complexity of the restriction.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory W Mitchell

Examiner

Art Unit 1617

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER